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From Warnock to the Stem Cell Bank – Evaluating the UK's Regulatory Measures for Stem Cell Research

Abstract

The United Kingdom government regards its regulations for stem cell research as some of the most rigorous in the world. This paper chronologically outlines the important stages in the evolution of these regulatory measures over the past twenty years, including the Warnock Report, the Human Fertilisation and Embryology Act 1990, the subsequent series of reports and consultations, and the establishment of the UK stem cell bank. Attending both to the discursive framing of stem cell research and the ethical issues faced, an assessment is made in terms of the appropriateness, adequacy and effectiveness of the UK's regulatory measures. Although institutional learning is detected in areas such as improving public engagement, the UK regulatory process has been open to the accusation of a scientific community regulating itself. This paper recommends that in order to avoid any possible complacency further improvements in public inclusiveness and interdisciplinary representation on regulatory committees should be sought.
Key Words: Science, Society, Stem Cells, Regulation, Consultation, Government.

The United Kingdom is often portrayed as one of the most liberal environments for Stem Cell Research (SCR hereafter) and whilst this is increasingly challenged by the emergence of research in countries such as South Korea[1] and the public/private divide[2] in the United States, the UK remains at the forefront, and so well placed to exploit any possible therapeutic applications. The development of the regulatory and legal framework in the UK, like that in other countries, is shaped to an extent by national cultural contexts which may or may not be in tension with emergent transnational or global regulatory frameworks within, for example, the European Union or the United Nations. This paper charts the evolution of the regulatory apparatus in the UK in regards to SCR in order to probe the history and context of this process as well as to assess its preparedness for the future. Moreover, in analysing the appropriateness, adequacy and effectiveness of the UK regulatory and legislative structure in regard to human SCR, problems, solutions, and possible failures, including potential lessons for Europe will be outlined.

Although not the main focus of this paper I shall begin by briefly situating UK regulation on SCR within the context of the European Union. The controversy of such regulation occurs largely through the reduction of the issue to that of the regulation of embryo research. This framing of the issue is of course up for contention. However it is at least partly down to research in identifying embryos as the best source for *pluripotent* stem cells – that is to say, those which may be open to the most varied degree of differentiation and so, it is hoped, the best therapeutic potential, that frames the issue. In spite of this one might still wish to question this reductionism since other research may in the future show the utility of non-embryonic sources of stem cells or even success in the goal of manipulating cells into acts of 'self-reprogramming'[3]. Even present research into stem cells occurs on non-embryonic sources such as cadaveric fetal tissue and therapies have already been used from umbilical cord stem cells. It is thus misleading to narrow the debate to embryos when we discuss stem cell regulation but it is such a course of events which has also inevitably entailed the regulatory re-amplification of prior arguments about the status of the embryo, more familiar to debates around abortion

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1 In early 2004 South Korean scientists successfully cloned thirty human embryos for use in SCR, for further information, see http://news.bbc.co.uk/1/hi/sci/tech/3480921.stm

2 Although the USA is often see as a restrictive nation for SCR due to the current influence of the religious right on the Bush administration, it allows privately funded research. Moreover, there is increasing power at the state level (California and New Jersey to date) to regulate in favour of embryonic SCR.

3 The information technology metaphor applied to the human body is, of course, problematic for what it may be saying about the organic human.

rights. This construction may be deemed further problematic in that ethical debates around embryos are prone to take place in a disembodied manner which abstracts them from women's bodies. If SCR is to an extent to rely upon the altruistic donation of embryos from women and/or couples undergoing in vitro fertilisation (IVF) or pre-implantation genetic diagnosis[4] (PGD), this seems like an important oversight.

The likelihood of European harmonisation in a permissive direction on SCR is at present compromised by a polarisation which largely revolves around this issue of embryo research. For example, the comparatively permissive countries of the UK and Belgium[5] presently stand in marked contrast to Germany, Austria and Italy. Whilst presumably harmonisation would make the EU an attractive location for economic investment and expertise in SCR and embryology generally, it is presently unlikely in a European regulatory environment which respects both pluralism and subsidiarity. Indeed the issue provides a good example of the latter as, in this case, indicative of different cultural histories and religious traditions. In spite of this pluralism there is, as Solter et. al. point out, economic pressure on more prohibitive countries not to lose out on both the prestige of novel science and potential economic advantage, consequently they hypothesize a gradual move toward an EU harmonisation on allowing embryo research (2003, 152/153). Recent evidence in support of their hypothesis is mixed and their prediction principally assumes an economic determinism. For example, new restrictive Italian legislation, which was condemned by the European Society of Human Reproduction and Embryology, offers a high degree of protection to embryos, banning PGD and restricting IVF[6]. Also in December 2003 EU research ministers failed to agree on whether to spend EU money on research with new embryonic stem cells, but agreed to assess each new application on a case by case basis within its 6th Research Framework Programme (FP6). Such developments then cast doubt on a move toward permissive EU harmonisation and it is against such a backdrop that UK regulations, in particular on *embryonic* SCR, stand out as a good potential basis for capturing both scientific research expertise and prestige; as well as the potential of economic advantage. The critical moment in the UK with regards to permitting research on embryos and so enabling embryonic SCR were the regulations that were passed in 2001 as additions to the Human Fertilisation and Embryology Act, 1990 (HFE Act hereafter). This paper will now focus on the evolution of the UK regulatory apparatus leading up to and since this point in time.

The Warnock Report and the 1990 HFE ACT

In 1978 the UK was the location for the birth of the first IVF baby. This can ultimately be seen to have had important consequences for the regulation of embryonic SCR. In an interesting parallel to what we have witnessed more recently in relation to scientific developments such as cloning, the first IVF baby brought into relief a 'legal vacuum' (Franklin, 1999: 61) around practices related to assisted conception. In spite of the initial vacuum the UK had a head start in comparison to other countries in thinking through the legal, social and ethical issues around IVF. A committee was appointed by the government in 1982 and published in 1984, after the name of its chair, The Warnock Report[7]. Although a general report on assisted conception the most contentious of its recommendations related to the issue of embryo research. The recommendations of the Warnock Report which later formed the basis of the HFE Act 1990, devised regulations for the treatment of embryos in IVF research and practice. These recommendations carried with them an ethical compromise at a point between sacralisation and instrumentalisation, and set the early context for what would later regulate SCR. This UK position which has been referred to as the 'proportionality' position (Solter et. al., 2003: 123), affords the embryo a proportional moral status, which is neither an absolutist statement of intrinsic value nor a wholly perspective of open utility. This is of course a position which allows research on embryos within limits. Thus the Warnock Report recommended that *"The embryo of the human species should be afforded some protection in law" (1985: 84)* and crucially that *"legislation should provide*

4 Pre-implantation Genetic Diagnosis is a form of early pre-natal diagnosis performed on couples who are at risk of giving birth to a child with a serious disorder, for example, a sex linked condition. PGD allows a 'healthy' embryo to be selected from a sample, and so like IVF produces a number of 'surplus' or 'spare' embryos.

5 In April 2003 Belgium passed legislation allowing the creation of embryos for research (for further details see Pennings 2003).

6 This was passed by the Italian Senate on 11th December 2003, see http://news.bbc.co.uk/1/hi/world/europe/3311031.stm

7 This was also published in 1985 as 'A Question of Life – The Warnock Report on Human Fertilisation and Embryology'. It is from this version that I quote.

that research may be carried out on any embryo resulting from in vitro fertilisation, whatever its provenance, up to the end of the fourteenth day after fertilisation, but subject to all other restrictions as may be imposed by the licensing body" (ibid.). Whilst the former recommendation expresses the 'proportionality' position, the latter fixes that limit of utility at fourteen days. As we shall see, although intended at first for assisted conception research this limit has come to be a foundational definition for all research involving embryos and now applies to scientists seeking to derive pluripotent stem cell lines. Moreover, the 14 day limit has found its way onto the statute books of other countries such as Sweden, Finland, the Netherlands, Greece, Spain and most recently Belgium. On the face of it the 14 day limit was based upon at least two observations from developmental embryology. First it is argued that since twinning of an embryo only occurs prior to fourteen days it is more difficult to conceptualise the embryo as a distinct individual during that period. Second fourteen days has been identified as the time at which the embryo develops a 'primitive streak', the beginnings of systemic cell differentiation and the formation of what will be the neural system. Some commentators and indeed some regulators who have employed this limit have conceded that it is in part an arbitrary standard. The point on twinning could be seen as a weak argument since it is a relatively rare occurrence and so it would seem a good general principle that in most cases the embryo prior to fourteen days exhibits a strong degree of potentiality for ultimately being born as an individual[8]. Moreover it seems a strange fetishization of the individual to assume that the moral worth of one individual would be greater than that of two. It has also been suggested that the fourteen day limit was more research led rather than based upon scientific facts or ethics given that that was the time for which embryos could be kept alive *in vitro* (Fleming & Pike, 2002).

In spite of this arbitrariness the limit stood and the definition coalesced and spread. It would influence the terms of the debate in the mid to late 1980s in the run up to the HFE Act. As Franklin recounts this time saw the emergence of pro-life groups opposed to either IVF itself or to the research upon, or disposal of 'spare' embryos (1999: 62). This inspired a concerted strategic response from the Medical Research Council (MRC) and other parts of the UK science establishment in an attempt to ensure that the then forthcoming Bill would legalise embryo research. One element of this was the construction of the 'pre-embryo', a category that was wholly enabled by the prior fourteen day limit of the Warnock Report. Franklin pinpointed the 'birth' of the term 'pre-embryo' to a 1987 *New Scientist* article written by an embryologist from the MRC (op. cit. pp. 65-67). The description of the embryo before fourteen days as a 'pre-embryo' or the variant 'early embryo' had the effect of moral devaluation, and in as much, added a veneer of scientific legitimation to the case for embryo research[9].

Although the Warnock Report and its media representation contributed to the amplification and polarisation of debates on embryo research, as well as a partial return to abortion ethics, after much debate its recommendations finally formed the basis for the HFE Act 1990. This Act led to the establishment of the Human Fertilisation and Embryology Authority (HFEA) which in addition to its role in regulating and overseeing IVF was given powers to license embryo research. At this stage the Act only permitted research on embryos *"which increases knowledge about the creation and development of embryos, or about disease, or enables such knowledge to be applied"*[10]. Such research was legitimated for the following five purposes: (i) promoting advances in the treatment of infertility, ii) increasing knowledge about the causes of congenital disease, (iii) increasing knowledge about the causes of miscarriages, (iv) developing more effective techniques of contraception, or (v) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation[11]. Licenses can only be granted if the HFEA is satisfied that any proposed use of embryos is necessary for a given research project. The Act also includes precise rules of consent by which no embryo can be used for research *in vitro* without each gamete donor granting specific consent for a designated research pur-

8 It is of course a slightly different argument as to whether any embryo or foetus could be considered an individual due to fundamental reliance on its mother.

9 Although the concept of a 'pre-embryo' was an important actor in the rhetorics of the debate it is worth noting that in the HFE Act, 'embryo' is defined as 'a live human embryo where fertilisation is complete', that is to say, prior to fourteen days. The term 'early embryo' could be seen to operate in a similar, if perhaps not quite as instrumentalising a manner.

10 The Act is available online, for this line please refer to paragraph 3, point 3 at http://www.legislation.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_4.htm#sdiv2

11 All of this specific section is to be found at http://www.legislation.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_4.htm#sdiv2

pose. Moreover it states that donors must receive an opportunity for counselling on possible implications for consent to be valid, and that donors must be provided with relevant information. Storage of embryos is dependent upon being granted by the female gamete donor. The regulations for consent are rigorous but omit issues of timing (see Herder 2002: 16/17) which are important since the context at which consent is sought may be relevant to a person's decision and the phrase 'relevant information' is arguably somewhat open ended[12]. It should be noted that the HFE Act 1990 makes no mention of stem cells and it is not until the late 1990s that a consultation process begins which culminates in the statutory instrument being added to the Act - legalising embryonic SCR in January 2001[13]. This paper shall now review this consultation process, outline challenges and reviews of the statutory instrument post-January 2001, and finally subsequent developments, notably the establishment of the UK Stem Cell Bank in January 2003[14].

One criticism that may be made of UK regulatory measures of SCR is that the scope of public consultation has not had the same reach as in other European countries such as Germany or Sweden. For example, there has been no concerted public engagement exercise on the scale of the 2003 GM Nation exercise (the consultation on genetically modified crops). Yet this may reflect the governmental attitude to consultation which it has gradually begun to take more seriously in recent years. Thus the consultation on SCR, particularly that initiated in the late 1990s around the use of 'therapeutic cloning' techniques followed the model[15] of consulting with larger bodies such as religious groups, scientific bodies and interest groups. The danger of such a narrow consultation is that it does not adequately respect societal plurality. In a similar respect to bioethics bodies and religious groups it is relevant to probe which disciplines and/or ethical approaches are given most weight in the former, and which theological perspectives are heard in the latter.

The HFEA/HGAC Consultaion

In January 1998 the HFEA and the Human Genetics Advisory Commission (HGAC[16]) launched a joint consultation on human cloning entitled, *'Cloning Issues in Reproduction, Science and Medicine'*. Although about cloning generally this consultation was of direct importance to the future of embryonic SCR in the UK since it sought to elicit views upon the potential therapeutic benefits of cloning as a technique for deriving stem cells. Indeed it is at this point in the regulatory process that one may observe the discursive strengthening of a differentiation between therapeutic and reproductive cloning. This has been referred to as the *"rhetorical severing of therapeutic cloning from reproductive cloning"* (Parry, 2003: 147). In its introduction the consultation states, *"It is important to make the distinction between human embryo research, which may be permitted under license under the 1990 Act and reproductive cloning, where an embryo is implanted into a women's womb"* (HFEA/HGAC, 1999: 15). Thus although one type of human embryo research and reproductive cloning essentially involve the same technology of cell nuclear replacement (CNR), this and subsequent regulatory and legal documents differentiate the two in terms of intentionality and argue against any 'slippery slope' critique by the recommendation, and then enactment, of an explicit ban on the implantation of a cloned embryo into a women's womb[17]. The main purpose of the consultation document in respect to therapeutic cloning was to ask for views on whether any additional ethical concerns may be brought into play by adding to the provision and scope of embryo research contained in the HFE Act 1990. The consultation paper was disseminated and responses were invited until April 30th 1998. Just under 200 responses were received with about 40% from individual members of the public and the remainder from professional bodies, religious organisations

12 The section of the Act on consent is available here http://www.legislation.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_5.htm#sdiv3

13 Statutory Instrument 2001 No.188 [The Human Fertilisation and Embryology (Research Purposes) Regulations 2001] may be viewed online at http://www.legislation.hmso.gov.uk/si/si2001/20010188.htm

14 The Stem Cell Bank was officially opened for the deposit of samples in May 2004.

15 The difference I am trying to allude to here reflects differences in depth since some consultation exercises will axiomatically take certain bodies as public representatives, or more ambitiously as in GM Nation, some will seek a more direct public engagement and attempt to involve those who had otherwise been disinterested on a given issue.

16 The HGAC along with the Advisory Committee on Genetic Testing and the Advisory Group on Scientific Advances in Genetics were wound up in a governmental streamlining exercise in 1999; their respective roles being taken on by the new Human Genetics Commission (HGC).

17 The advantage of using therapeutic cloning to create embryos for stem cell applications is that unlike embryos obtained form IVF or PGD they are an exact match with the donor. The UK ban on reproductive cloning is contained in the Human Reproductive Cloning Act, 2001.

and lay groups. Once collated the HFEA and HGAC published its report of the same name in December 1998. Introducing its findings on the therapeutic cloning section the report states *"Some thought that the distinction between reproductive cloning and therapeutic cloning was arbitrary, others just responded negatively to anything described as "cloning" and some were upset at the description of identical twins as a 'natural form of cloning'. It is clear that the word 'cloning' carries an automatic stigma for many because of its association with imagery such as that portrayed in Brave New World. To avoid this confusion this section of the report has been headed 'Therapeutic Uses of Cell Nucleus Replacement (CNR)' and concentrates on new techniques which might be developed to treat serious medical conditions"* (1998: 19). This is a curious passage since it seems to respond to fears of intentional obfuscation with a further change in wording that seeks to escape the perceived negative connotation of 'cloning'. Moreover, the change in terminology instigated here would later be criticised in the House of Commons in November 2000 when Ann Winterton MP argued that the UK regulatory apparatus had substituted 'cloning' for the more morally neutral 'cell nuclear replacement'(HC Debate 17 November 2000, column 1196)[18] The implication then is not that the change in terminology was, as the above passage suggests, to 'avoid confusion' but that it was more about constructing consent to a new technique by using less stigmatised language. Strategic games with language aside, the HFEA/HGAC report summarised findings from its consultation and found that whilst 80% were against reproductive cloning, 55% thought that there were scientific areas that might benefit from research involving CNR, compared with 10% who did not (op cit, p. 38). The report recommended that the government could introduce more explicit legislation banning reproductive cloning, and of more relevance to SCR, that two further research purposes be added to the five already specified in the HFE Act 1990 (see above). These two extra purposes were i) developing methods of therapy for mitochondrial disease, and ii) developing methods of therapy for disease or damaged tissues or organs. The latter purpose flags the regenerative potential of stem cells.

In June 1999 the government published a positive response to the HFEA/HGAC consultation and report. Tessa Jowell MP, the then Minister for Public Health, articulated that *"The Government reaffirms its policy that human reproductive cloning is ethically unacceptable and cannot take place in this country. However, we recognise that regulations to allow therapeutic research should be very carefully considered"*[19]. This stated need for further careful consideration led to the government instigating an 'independent expert advisory group' to be chaired by the Chief Medical Officer, Professor Liam Donaldson. This became the next stage in the regulatory process which was now becoming increasingly specific to the issue of SCR and its associated legal and ethical issues. Other similar reports were concurrent and before the Donaldson Report was published in June 2000, the Nuffield Council on Bioethics produced a discussion paper entitled 'Stem Cell Therapy: The Ethical Issues' in April 2000.

The Nuffield Report fed into what would become the Donaldson Report when it gave a preliminary presentation of its findings to the Donaldson advisory group in November 1999[20]. In the absence of any government instigated bioethics body, akin to the US model, the Nuffield Council on Bioethics is the most prominent UK national body. It describes itself as an independent body which receives its funding from the Nuffield Foundation, the Medical Research Council and the Wellcome Trust. Yet it offers its own definition of bioethics since its objects of interest are typically focussed upon new innovation in science and a large proportion of its members are scientists. At the time of the Stem Cell Therapy report, at least half of it's 14 members were scientists. If the role of bioethics is to provide a thorough and interdisciplinary examination of science and technology it is reasonable to draw attention to the low number of philosophers and absence of social scientists on the Council, as well as its funding base.

In common with the HFEA/HGAC view the main recommendation of the Nuffield report was that the government should provide additional research contexts for embryo research to those already specified in the HFE Act 1990. On the question of creating new embryos for research the Council thought there was 'no compelling reason' as long as 'spare' embryos were available from IVF, but that this should be kept under review[21]. This was a similar

18 See also Sleator (2000) and Parry (2003).

19 The text of the Government response is available online at http://www.dh.gov.uk/ PublicationsAnd Statistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4025446&chk=ozNabK

20 The Donaldson Report also received advisory submissions on therapeutic cloning from groups such as The Royal Society, but I focus here on the Nuffield submission due to its ethical content.

21 It should be noted that when the Nuffield Report was written a number of embryos had already been created

position to the US National Bioethics Advisory Commission (NBAC), but one that would be overriden by the subsequent Donaldson Report (see below and Holm, 2002: 505). Furthermore, the report offered useful recommendations in the areas of consent, patenting and on the drivation of stem cells from fetal tissue. Due to the theorised immortality of stem cell lines the Council argued that the use of embryonic tissue inspired novel consent issues and so argued that embryo donors should be asked explicitly for consent to that research and subsequent therapeutic use of that stem cell line[22]. This concurred with the recommendations of NBAC that donors would be told that there would be no medical benefit from being donors, that sources of funding and expected commercial benefits from the research be disclosed, that no donated embryos would be implanted in a woman and that research would include the destruction of their embryos. Looking ahead to potential therapies and the establishment of methods for generating stem cell lines the Council argued strongly against the granting of 'over generous patents with strong claims' as they may act to restrict stem cell research overall. On this issue it was not until April 2003 that the UK Patent Office issued a clarifying notice entitled 'Inventions involving human embryonic stem cells'[23]. Stressing consistency with the Patents Act 1977 this stated that both 'processes for obtaining stem cells from human embryos' and 'human totipotent cells' were not patentable, the latter due to the potential of such cells to develop into an entire human body. However it did rule that patents would be issued for 'human embryonic pluripotent stem cells' arguing that their commercial exploitation would *"not be contrary to public policy or morality in the United Kingdom"* (see end. 21). Laurie has questioned this totipotent/pluripotent patenting distinction given that the stage at which cells change from totipotency to pluripotency is difficult to pinpoint and that the former quality can only be demonstrated by growing them (2004: 63). Consequently future UK patents on stem cells will be required to carefully ensure that their research involves cells which are definitively pluripotent. Finally it would be hoped that the Patent Office would take on board the recommendation of the Nuffield Report to prevent patents that are too general.

The Nuffield Report also commented upon a significant non-embryonic source of stem cells in its recommendations for the derivation of stem cells from fetal tissue. At this point it refers back to the 1989 Polkinghorne guidelines which comprise a non-statuatory code of pratice for research uses of fetal tissue obtained from abortions. The report points out that in contrast to embryonic tissue, the therapeutic and research use of fetal tissue does not require a license but each proposal is regulated by research ethics committees. It re-emphasises the importance of the Polkinghorne stipulation that a women's decision to abort and any discussions of therapeutic uses of fetal tissue must be separated so as not to incentivise abortion, as well as the Polkinghorne consent principle that a general written consent should be obtained from the mother for *all permissable* research purposes. This consent procedure also involves the provision of 'counselling and comprehensible information'. Whilst concurring with the Polkinghorne regulations generally the Nuffield Report advised that since the Polkinghorne general explicit consent principle conflicts with a specific consent procedure of informing donors that donated tissue *will be used for SCR* (as with embryonic tissue) the question ought to be considered further by the Donaldson Report.

It is interesting to note that in a later HGC consultation (on Human Genetic Databases, named 'Whose hands on Your Genes?') Professor Robert Shaw of the Royal College of Obstetricians and Gynaecologists is very critical of The Polkinghorne Guidelines including its consent principle. Specifically Shaw argues that a general explicit consent in which no information is offered is *"an anachronism in an open, modern society, opposed to all other instances of research consent, harmful to women who often take an interest in the research and who derive psychological benefit from the knowledge that they may be helping scientific research and mankind, and is likely to be contested in the courts"*[24]. It is perhaps surprising then at this stage of the regulatory process that the Nuffield Report did not raise some of these concerns, saying only that it would be 'consistent' for a specific special consent to be sought for the derivation of stem cell lines from fetal tissue. As long as this more open

for research purposes in the UK. Specifically between August 1991 and March 1999, 53, 497 embryos from IVF programmes were donated from and 118 were created for research (POST 2002: 4).

22 The Nuffield Council on Bioethics Report 'Stem Cell Therapy – The Ethical Issues' is available from http://www.nuffieldbioethics.org/filelibrary/doc/stem_cell_therapy2.doc

23 This is available at http://www.patent.gov.uk/patent/notices/practice/stemcells.htm

24 As of April 2004 The Polkinghorne Guidelines are currently being reviewed. Please refer to Professor Shaw's response at http://www.hgc.gov.uk/whoygconsultation_responses/rcobsgyn.htm

consent principle was not enacted at the wrong time, one could assume that it would not interfere with a woman's decision to have an abortion or not. However when the issue was taken up by the Donaldson Report later in 2000 it said little more than was stated in Nuffield concluding that the Polkinghorne Code of Practice should be reviewed to *consider* whether a specific consent should be sought from women when fetal tissue is used for SCR[25].

The Donaldson Report

The main focus of the report, entitled *"Stem Cell Research: Medical Progress with Responsibility"*, is very much upon *embryonic* SCR with the goal of extending the research purposes of the 1990 HFE Act. Although a report that considers both the legal and ethical aspects of SCR the Chief Medical Officer's Advisory Group assembled to compile the Donaldson Report was compiled predominantly of scientists, significantly more so than the Nuffield Report. Of the 14 individuals, 11 were scientists, 1 was a scientist/theologian/fellow of the Royal Society (John Polkinghorne), only 1 was an ethicist (Alistair Campbell) and only 1 was a legal specialist (Derek Morgan). Scientific representation within the regulatory process of SCR is of course vital - yet with such a skewed representation the UK science establishment leaves itself open to accusations of self-policing. Moreover there is the associated danger that it may miss important ethical or social aspects.

The Donaldson Report situated itself temporally within a regulatory timeline of the Warnock Report and the 1990 HFE Act. Understandably its aim was not to repeat the debates contained therein on the ethics of embryo research but to consider specifically whether the use of embryos for the derivation of stem cells presented any new ethical issues. Drawing upon the previous decisions of the Warnock Committee and the rulings of the 1990 HFE Act the report concludes that the proposed extension of the research uses of embryos did not raise fundamentally new issues: *"The position encapsulated in the 1990 Act is that it is permissible to undertake research which involves the use (and inevitable destruction) of embryos where there is good reason to believe that such use will lead to improvements in, for example, infertility treatment or the understanding of congenital disease"*[26]. Indeed one can argue that since SCR could lead to therapies for such a wide range of conditions that its public health reward would make the proposed new research use of embryos more ethically sound than those already legalised under the HFE Act[27] (albeit with the ethics resting somewhat uncomfortably on the word 'could'). The Donaldson Report then goes on to consider the ethics of creating embryos for research, an act which is generally taken to involve a deeper level of instrumentality. Although 'spare' embryos from IVF and PGD provide sources of research embryos, the creation of embryos specifically using CNR provides an opportunity to, in the words of the report, *"investigate the mechanisms for reprogramming adult cells and to establish whether tissue can be developed which is compatible with the intended recipient"*[28]. The report concluded, as with the ethical trade off with other prior uses of embryos, that their creation by CNR should be permitted owing to its therapeutic promise as long as it was rigorously controlled by the HFEA. Licenses should only be granted when the creation of embryos were a necessary element of the research. This formed one of nine recommendations made by the Donaldson Report. Alongside the recommendation that research using embryos to increase understanding about human disease and disorders should be permitted formed the thrust of the report. Other important elements were the reiteration of the illegality of reproductive cloning, the need for *specific* consent to be sought from individuals whose eggs or sperm are used to create embryos which are donated for SCR, a call for UK research councils to establish a programme for SCR[29] and to consider the feasibility of establishing centralised collections of stem cell lines for research – later to become the UK Stem Cell Bank.

The government response to the Donaldson Report was to accept its recommendations in full. Later in 2000 the government introduced these regulations for parliamentary debate where a free vote

25 This in spite of John Polkinghorne being part of the Donaldson Report Advisory Group. See Paragraph 4.29, on page 42 of the Donaldson Report 'SCR: Medical Progress with Responsibility' which may be viewed online at http://www.dh.gov.uk/assetRoot/04/06/50/85/04065085.pdf

26 Paragraph 4.12 p.39.

27 See Paragraph 4.27 p.41/42.

28 Paragraph 4.14 p.40.

29 In 2002 the government provided £40m. The MRC received £26 million, the BBSRC received £10 million and the ESRC £1.8 million. The physical sciences Councils received small allocations to help develop key technologies. Successful applicants to each research council call for proposals began their research in mid 2004. In May 2004 a total of 57 multi-disciplinary research grants were awarded, see http://www.mrc.ac.uk/index/public-interest/public-press_office/public-press_releases_2004/public-27_may_2004.htm

was permitted. In the run up to this debate several oppositional groups gave responses on the subject. LIFE, which describes itself as the UK's leading pro-life charity[30] articulated its opposition by first arguing for alternative sources of pluripotent stem cells and second by aligning itself with the more cautious European position on 'therapeutic' cloning. The Society for the Protection of the Unborn Child (SPUC[31]) also allied itself to a European context, supporting a resolution from the European Parliament that had accused the UK separation of 'therapeutic' and 'reproductive' cloning as a 'linguistic sleight of hand' (see Sleator, 2000: 49). SPUC was also unhappy that the HFEA included a 'strong representation from the test-tube baby industry' echoing the previous criticism of 'self-policing'. The UK Catholic Church was also opposed, whilst the Church of England and the Chief Rabbi offered cautious approval. LIFE and SPUC were strategically correct to avoid arguing against the proposals on the grounds that embryo research was morally wrong (even though this was and is their underlying position) since the response would have been simply that that debate had already taken place at the time of Warnock and the 1990 HFE Act. By shifting their critique to the sphere of science and by proffering a European alignment they could have more chance of being heard and less chance of being dismissed as 'irrational'. However, in the UK regulatory process, dominated as it has been by scientists, pro-life positions fundamentally against embryo research are portrayed as one extreme end of a moral continuum – the other being unfettered instrumentalism. Thus the Donaldson Report was able to present its own permissive position as the rational middle ground between two extremes in a similar manner to Warnock (see Kerr, 2003: 120). Of course one might point to the minority status of the pro-life view in the UK and SPUC's own linguistic sleights of hand in describing an embryo or foetus as an 'unborn child' as a defence of its regulatory marginalisation. However, whilst it would not have been democratic, one assumes, for this position to have held sway in the UK it is still worth underlining its 'management' within the wider regulatory process.

The House of Lords select Committee on SCR

In spite of some similarly articulated opposition in the House of Commons debate the additional statutory instrument to the 1990 HFE Act was passed in January 2001 with the three further contexts under which embryo research could be licensed by the HFEA worded as i) increasing knowledge about development of embryos, ii) increasing knowledge about serious disease and iii) enabling any such knowledge to be applied in developing treatment for serious disease. The addition of the word 'serious' was to avoid what may be seen as more frivolous applications of embryonic SCR, but would later cause problems owing to a lack of definition of what constituted 'serious disease'. On the 7th March 2001 the House of Lords agreed a motion appointing a Select Committee to oversee both the rapidly changing field of SCR and to report back on issues related to research arising from the new statutory instrument. Moreover, unlike the Donaldson report, the committee took an interest in reviewing whether some of the conclusions of the Warnock Report and the 1990 HFE Act still applied. The committee was asked to compile its own report which also became a significant public consultation exercise in the context of the UK regulatory process outlined in this paper[32]. In April 2001 the committee issued a call for evidence on the ethical, legal, scientific, medical and commercial issues surrounding the regulations as they now stood. This stage represented a commendable part of the UK regulatory process on SCR. Instead of taking some regulatory respite after the passing of the additional statutory instrument the formation of the Select Committee introduced a deeper stage of regulatory self-reflexivity as well as the widest public consultation on the subject to date. Arguably this was related to a new stress on the importance of both transparency and public consultation in the Labour government at this time. The Committee took the remainder of 2001 to undertake the accumulation of evidence and the subsequent compilation of their report.

In the meantime a case brought by Bruno Quintavalle of the Pro-Life Alliance challenged the government on whether the 1990 HFE Act had in fact any jurisdiction over cloning research. Quintavalle argued that an embryo produced by CNR did not comply with the definition of an embryo under the Act because its creation did not involve fertilisation. The High Court agreed decid-

30 http://www.lifeuk.org/

31 http://www.spuc.org.uk/

32 The report by the House of Lords Select Committee on SCR is available online here http://www. parliament.the-stationery-office.co.uk/pa/ld200102/ldselect/ldstem/83/8301.htm and the list of organisations and individuals who responded to the call for evidence can be found in Appendix 3 here http://www.parliament.the-stationery-office.co.uk/pa/ld200102/ldselect/ldstem/ 83/ 8313.htm

ing the challenge valid. The implication of this was that now no forms of cloning fell under the 1990 HFE Act. Consequently the government acted rapidly to ban reproductive cloning, something it thought it had already done, with the passing in a little over two weeks later of the Human *Reproductive* Cloning Act 2001[33]. This left a considerable problem over the use of CNR for 'therapeutic cloning' and the government simultaneously launched an appeal over the court's decision. On January 18th 2002 the High Court ruled in favour of the government's appeal justifying its decision on the basis of 'purposive construction'. This doctrine, often used in patent rulings, allows the original context and intentionality to be taken into account. This was ruled to be relevant in this case since CNR had not yet reached viability in 1990. In the opinion of the High Court *"embryos created by CNR fell within the genus of those of the Act"* (R v Secretary of State for Health ex parte Quintavalle, 2001) and to rule otherwise would be to defeat the purposes of that Act[34]. The Society for the Protection of the Unborn Child (SPUC) accused the Court of interpreting the law in a very elastic way and that extending the definition of an embryo should be a Parliamentary decision, not a Court matter. This was a fortunate ruling for the government and research community avoiding the need for a more radical revision of legislation.

This case and the concurrent consultation by the House of Lords Select Committee made this period a busy time for the UK regulatory procedure. The month after the High Court ruling the select committee presented it's report. The Committee's wider reach in terms of public consultation, alluded to above, brought in a range of opinion beyond the scientific establishment and pro-life groups that had been the familiar actors in the regulatory process. Oral and/or written submissions were given by a range of patient groups, bioethics centres, and what may be described as secular oppositional groups such as Human Genetics Alert and the Institute of Science in Society[35]. On the more critical side there remained what was arguably an important gap in the consultation process in that there continued to be a marked absence of pro-feminist groups, or feminist bioethicists. Given the overlap of SCR with assisted conception technologies of IVF and PGD, together with the invasiveness of such procedures on women's bodies this is an exclusion that is difficult to account for. Rose (2004) was justified in her criticism that throughout the UK regulatory process women have been underrepresented on the various committees (The House of Lords Select Committee was, as she acknowledges, an exception with women forming the majority of its membership). However it is simplistic to assume that greater female representation will entail a better airing of issues of special relevance to women. For example, in spite of Rose's contention otherwise, the House of Lords Select Committee generally took the same view on the creation of embryos for research as prior regulatory committees (see below). The process of ovulation induction using gonadotrophin drugs to artificially stimulate a women's ovaries to overproduce eggs may carry side effects and lead to the development of Ovarian Hyperstimulation Syndrome. This raises its own ethical issues for assisted conception technologies yet the lack of discussion of their gendered experience has been surprising in the regulatory process. Even if embryonic SCR does not directly at this point in time increase the number of women undergoing ovulation induction, its normalisation has the potential to indirectly provide further rationale for the technological framing and intervention into women's bodies. Since SCR has been regulated in the UK by adding to pre-existing legislation aimed at IVF, rather than having it's own separate legislation, and that both are controlled by the HFEA, the technologies are more likely to evolve *inter*dependently with the result being a mutual co-naturalisation. The inclusion of novel critical voices in the Select Committee consultation then was a step in the right direction but arguably did not go far enough. The terms of the debate have also received criticism for a focus on the status of the embryo portrayed as abstract from women's bodies or a reduction of women's ethical significance to being just about providing consent (e.g. Dickenson, 2002). Whilst the *literal* removal of embryos and eggs from women's bodies may inspire one strand of oppositional voice the reduction of ethical debate to individual issues of consent and privacy does risk a closure of other important issues. For example, a fuller assessment of the social and ethical impact of SCR could examine more closely its potential impact upon women undergoing assisted conception technologies and begin to consider consulting on the long term impact it may have on questions of

33 This very succinct act is available to view online at http://www.legislation.hmso.gov.uk/acts/acts2001/20010023.htm

34 Quintavalle in turn unsuccessfully challenged this ruling, with the High Court dismissing his appeal in March 2003.

35 The anti-therapeutic cloning stance of the Institute can be viewed here http://www.i-sis.org.uk/ISISsubmission.php

'enhancement' related to ageing and the human lifespan.

The Select Committee consultation and report attempted to probe a series of old and new questions. These included whether the additional purposes in the 2001 Regulations raised issues of principle different from the purposes specified in the 1990 Act, whether international commercial developments such as e-commerce and patenting changed the context of the debate in the UK, whether the potential of non-embryonic sources of stem cells had improved and whether the HFEA required any additional regulatory guidelines to assist its work in issuing research licences.

Sections of the report concluded by reinforcing many of the ethical principles and decisions of earlier regulatory stages. For example its review of the status of the 'early embryo' (it is of course important to note that the phrase 'early embryo' had now received regulatory normalisation) backed up both the Warnock and HFEA view that research ought to be permitted and that creating embryos for research ought only be allowed if there was a demonstrable and exceptional need. But a significant amount of the report was geared toward new developments. For example, it reviewed recent research on adult stem cells (including those obtained from the placenta and umbilical cord), concluding that they were promising in terms of cell type differentiation potential. Consequently government funding of these avenues was strongly encouraged. Importantly the report also concluded that CNR should be allowed for basic research purposes and satisfaction was expressed with the regulatory powers of the HFEA in regards to preventing the application of CNR for reproductive cloning. Moreover, the report deliberated over the ambiguity that took place after the introduction of the word 'serious' in the phrase 'serious disease' in the 2001 statutory instrument. The Committee recommended that the government and the HFEA draw up guidelines as to what constituted serious disease. Recommendations on consent were to standardize the separation of clinical and research roles in egg or embryo donation. This came after the Committee had visited several clinics and had been satisfied that consent was being sought openly and without pressure. The separation of these roles would further assuage any fear that moral pressure was a part of the consent process. Furthermore, given the potential 'immortality' of embryonic stem cell lines it was advised that when informed consent was specifically sought for use of embryos for SCR that no specific constraint should be placed on the future use of those cells. The report also indicated what would become the next step in the regulatory process with its endorsement of the government's decision to establish a UK Stem Cell Bank, under which all research projects granted license by the HFEA would be required to deposit any stem cell lines generated. A regulatory shift could now be noted as the focus began to move downstream, to storage procedures and in a very preliminary sense, therapeutic application.

Also in February 2002 the HFEA granted it's first two licenses for embryonic SCR on 'spare' embryos from IVF. The first actual human embryonic stem cell lines to be derived in the UK resulted from research on 'spare' embryos consensually donated from PGD in 2003. It is now thought that such embryos will be an important future source for stem cell line derivation. As the research team stated, given that PGD embryos do not actually come from infertile couples they *"may be of better quality than fresh embryos surplus to assisted reproduction cycles"* (Pickering et. al., 2003: 353). In August 2004 the HFEA granted its first application for the use of CNR in embryonic SCR[36].

The government response to the Steering Committee's report in July 2002 was enthusiastic with every recommendation endorsed. The response paper was a confident declaration of the robustness of UK regulation on SCR illustrative of the government's view that the UK was *"ideally placed to be a leading force globally in this field"* (2002: 7). Much prior discourse received reiteration, for example, the government's confirmation that research on 'early embryos' must not extend beyond the Warnock 14 day limit. In response to the ambiguity of 'serious disease' the government decided that instead of compiling a guidance list the short term solution should be for the HFEA to assess this matter on a case by case basis. Reflective of the regulatory shift at this time a significant proportion of the response paper pertained to potential future developments including that under current legislation any clinical trials of therapeutic applications of SCR would be regulated by the Medicines Control Agency (MCA). However, in April 2003 the MCA and

36 This refers to the project taking place at the Newcastle Centre for Life, entitled 'Derivation of Human Embryonic Stem Cell Lines using Nuclear Transfer and Parthenogenically Activated Oocytes'. To date (August 2004) the HFEA has approved 10 licenses for embryonic SCR. Please refer to the very helpful HFEA web-site at http://www.hfea.gov.uk/Research

the Medical Devices Agency (MDA) were discontinued and a new agency of the Department of Health, The Medicines and Healthcare products Regulatory Agency (MHRA), came into being. As indicated in the Medical Research Council's Terms and Conditions[37] for research involving human stem cells *"patient trials of stem cell therapies require a clinical trials certificate from the Medicines and Healthcare products Regulatory Agency, and approval from a local research ethics committee"*. The House of Lords itself held a debate on its own Select Committee's Report in December 2002[38]. Although voting to accept the report, objections were made (by Lord Tombs) about the composition of the Select Committee, specifically levelling the complaint that no Lords opposed to the use of embryos had been chosen as members. This valid point indicated the continuity of this criticism throughout the UK regulatory process that both committees and advisory groups were already composed in favour of embryo research.

The UK Stem Cell Bank

The government indicated in mid 2002 that the Department of Health and the Medical Research Council had made progress on the establishment of the UK Stem Cell Bank. The remainder of this paper shall focus on the Bank regulations before finally moving briefly onto the government's response to the House of Commons Trade and Industry Committee's report on the UK Biotechnology Industry (2003). It was agreed by the government that all HFEA licensed embryonic SCR would be legally bound to deposit any resultant cell lines in the Bank ensuring tight regulation and an effective shared pooling within the research community. Moreover this would minimise the duplication of research and so any unnecessary further creation of embryos for research. In September 2002 it was announced that the National Institute for Biological Standards and Control (NIBSC) had been appointed to set up the UK Stem Cell Bank. It would be funded by both the MRC – 75% – and the Biotechnology and Biological Sciences Research Council (BBSRC) – 25%. The rationale behind the Bank was to provide a transparent, well regulated, standardised and quality-controlled location for embryonic, adult, fetal and other stem cell lines in the UK. Other important considerations were the centralisation of 'ethically sourced' lines and, as Pederson has argued, the contribution 'Banking' can play in finding ways to match stem cells with intended recipients (2003). Once banked such lines are open to both academic and commercial researchers, and also to researchers from overseas. As part of its governance structure the 'Steering Committee for the UK Stem Cell Bank and for the Use of Stem Cell Lines' was established in December 2002, and now meets four times a year. It has a varied membership including scientists, lay members, ethicists, a theologian and a social scientist. This makes it arguably the most diverse governance body to date in the history of UK SCR regulation. This forms the first tier of the Bank's governance structure which is completed by a Management Committee and User Liaison and Clinical Liaison Committees[39]. The Steering Committee is responsible for developing two codes of practice, one for the Stem Cell Bank, and one for the use of human stem cell lines. It is also responsible for reviewing all applications to deposit and access stem cell lines from the Bank. The Management Committee, which is comprised of scientists is concerned with the implementation of the codes of practice on the ground, the Bank's financial planning and day-to-day quality control issues. The User Liaison and Clinical Liaison Committees are both large committees created to ensure effective communication with the UK SCR community on issues related to the use of the Bank and the development of therapies for clinical application.

The ongoing development of both codes of practice are subject to public consultation. The consultation for the Stem Cell Bank code of practice was completed in October 2003 and responses were taken on board for the completion of the next draft. This consultation was open, with responses mainly from the science community, the biotech industry, royal colleges/societies, with a number of individual responses and some comments on ethics from the Nuffield Council[40]. Although not published, both codes were made available in draft form online

37 These Terms and Conditions, which specify how MRC grantees must work with the UK Stem Cell Bank and its Codes of Practice, are published online here: http://www.mrc.ac.uk/pdf-terms_conditions_stem_cells.pdf

38 This debate may be read here http://www.publications.parliament.uk/pa/ld199900/ldhansrd/pdvn/lds02/text/21205-15.htm#21205-15_head0

39 Here I summarise the terms of reference of these four committees of the UK Stem Cell Bank. For a fuller account please refer to http://www.mrc.ac.uk/prn/index/strategy-strategy/strategy-science_strategy/strategy-strategy_implementation/strategy-government_spending_review_initiatives/strategy-stem_cells/strategy-stem_cell_governance.htm

40 Personal Communication from Professor Andrew Webster (member of the Stem Cell Bank Steering Committee).

in April 2004. They remain as such since the consultation for the latter code on the use of human stem cell lines is ongoing and may lead to changes in the code of practice for the Stem Cell Bank. Both codes include the ethical principles by which the Bank shall be run. The Stem Cell Bank code describes an overarching principle of respect for *"human biological material which it curates"*, the physical separation of Bank staff from the process of securing donor consent and the responsibility of the Steering Committee Secretary to maintain the privacy of donor and recipient identity. The Secretary is also to be responsible for putting in place, with the Bank staff, an anonymised traceability system for linking donor information to the Banking stem cell lines so that donors may be identified in cases where adverse health data is detected (2004: 12). This is significant since although donors will not receive any financial reward they will be alerted to any health problems that their tissue samples may reveal (for example all donors will be tested for a range of diseases including HIV). A more detailed section on ethical principles is contained within the draft of the second code – on stem cell lines. This is a careful passage which is very specific about the regulation of donation issues and research ethics generally. It is clearly sensitive to public concerns over the tissue use of the deceased in the light of Alder Hey, and the forthcoming Human Tissue Bill 2004 aimed partly at addressing these concerns, currently before parliament. The code therefore includes the specific outline of how embryonic stem cell lines may be used, as decided by the Steering Committee. These are *"research which has the long term goal of helping to increase knowledge about serious diseases and their treatment (as in the 2001 HFEA Regulations), basic cell research which underpins these aims (as recommended in the House of Lords Report 2002), and the development of cell based therapies for clinical trials in respect of serious human diseases"* (2004: 17). Although generally throughout the history of the regulation of SCR in the UK it has been embryonic sources of stem cells that have been constructed as being most morally loaded, the code is novel in its expression of moral and ethical sensitivity to adult and fetal sources. The code argues that since such tissues may be obtained following the termination of a human life their use is indeed a matter of moral concern. Consequently in a policy not that dissimilar to the use of embryonic tissue the code states that *"adult or fetal somatic stem cell lines curated at the Stem Cell Bank may only be used for research leading to the development of therapies, or for clinical trials of human therapies, or for basic research which underpins these aims"* (ibid., p.18). Adding to the regulatory rigour the code specifies that Research Ethics Committee approval must be obtained *"as part of the application procedure for an HFEA research licence, for all research projects involving embryonic stem cells irrespective of whether the stem cells have been derived in the UK or elsewhere, for all research projects involving adult and fetal somatic stem cells, and for clinical trials of all stem cell derived therapeutic products"* (p.19). Although there is no explicit mention in the Human Tissue Bill 2004 of SCR the new government concern over the treatment of human tissues by the UK scientific community does indeed flavour the ethical principles of the Stem Cell Bank Codes. In addition, the derivation of stem cell lines from fetal tissue may be further regulated when the current process of revising the Polkinghorne guidelines is complete. One criticism of the codes of practice as they currently stand is their framing of ethical issues largely in terms of donation, consent and embryo status. Writing prior to the codes in 2003 a Hasting Center Report paper drew attention to the importance of justice issues on the sourcing of stem cell lines with regard to future tissue matching, ensuring an equitable degree of societal benefit from future therapies (Faden et. al., 2003). Although the use of CNR could solve the tissue rejection problem it is surprising at this stage that the stem cell lines code in particular does not include justice issues related to equitable beneficence.

A further input into the consultation was provided by an MRC commissioned study on consumer views of the Stem Cell Bank. Reflective of changing norms of science policy public consultations, both within government and the science community, this was an inclusive dialogical exercise that by employing qualitative methodologies yielded a rich and detailed response from its participants. The exercise took place between the summer of 2002 and autumn 2003. It consisted of 12 focus groups and probed views on SCR and donation. Although members of the public these group were targeted according to different perspectives and experiences. These comprised two groups of men and two of women who were blood donors or who carried an organ donor card or intended to leave their bodies to medical science; one group of men and one of women 'non-donors' who were not blood donors, did not carry an organ donor card or intend to leave their bodies to medical science; one group of men and two groups of women who had successfully received IVF treatment; and one group of men and two

41 This consultation was carried out by People, Science & Policy which describes itself as "an independent science policy consultancy that specialises in science and

groups of women undergoing IVF treatment[41]. One striking finding was that women who had undergone IVF tended to view their frozen embryos in kinship terms, as potential children for their existing children. The creation of embryos for research was generally seen negatively, but the derivation of stem cells from aborted foetuses was seen as more acceptable and even carrying a potential to provide some feeling of comfort to those faced with a difficult decision. Despite the inherent difficulties of specified tissue donation in regard to SCR several group members expressed a desire to be able to outline the diseases for which their donation would be used. Relatedly there was concern expressed from both donor and non-donor groups that only researchers working on 'serious' diseases should have access to the Stem Cell Bank. Although already then enshrined in UK law, this was perhaps sparked by recent research taking place on cosmetic applications of SCR outside the UK[42]. The UK regulatory structure is tight here but in a more global sense it will be important to keep an eye on such applications not just because they might infringe on patients' rights but also because of the occasional overlap between categories of the 'cosmetic' and the 'medical'. Arguably an accusation of 'trivial' uses of SCR faces a similar burden of explanation to the legally enshrined notion of 'serious' disease.

Conclusion

Both the Stem Cell Bank and the consultative way in which its codes of practice are being constructed add to the rigour and reputation of the UK for its SCR regulatory structure in Europe and beyond. This wider regulatory context will continue to remain important. In the UK government's November 2003 response to the House of Commons Trade and Industry Committee special report on the UK Biotechnology Industry[43] concern was expressed over the future possibility of European regulations stalling UK competitiveness in this sector. The response states in reference to SCR that "*The Government shares the view of the Committee that this advantage must not be undermined by developments at the European level. To tighten and add further hurdles to the regulatory system could be seen as a failing of a system which has undergone rigorous scrutiny in the UK*" (2003: 4). Clearly the UK government espouses a subsidiarity viewpoint in order to protect its own regulatory structure which it regards as setting the foundation for present and future UK competitiveness. In a blow to hopes of European harmonisation the response goes on to say that "*The Government has maintained throughout negotiations in Europe that the detail and application of ethical principles which reflect the religious and cultural diversity in Europe, are a matter for Member State legislation and not within EU competence*" (op. cit). Although religious opposition to embryo research in the UK has been present it has not been as strong as in other EU states reflective, relatively, of both the UK's secularism and weaker Catholic church. This allied with the head-start over regulating embryo research due to IVF and the custodianship of the UK regulatory process by the science establishment are, it may be suggested, the most overriding explanations for the comparative permissiveness of the UK SCR environment.

At the outset of this paper it was asked whether any lessons could be learned from the UK regulatory experience to date for other EU states. Perhaps the most commendable feature of the UK process is that it has exhibited signs of improvement as it has proceeded. For example this is seen especially in the gradual improvement of its public engagement and the increasingly diverse representation on regulatory committees. The codes of practice of the Stem Cell Bank also indicate both a preparedness for, and in their flexibility a responsiveness to, future developments. It ought to be cautioned that the regulatory process in a given country is in very significant ways tied to the specificities of cultural, economic and religious context, thus the notion that one country may have lessons for another requires qualification. Indeed a case can be made for lessons being drawn *from* other EU countries for the reach of public engagement on cloning and SCR. Undoubtedly a mutual exchange of lessons can be learnt from both respective strengths and weaknesses of different countries. Although there may not be harmonisation on the regulation of research, harmonisation on the best practice for achieving a democratic regulatory process may be a more realistic goal. The clearest regulatory weakness of the UK process centres around the accusation of self-policing in that the composition of past committees has been heavily skewed in favour of scientists who are likely to already favour SCR.

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society issues". Please refer to http://www.peoplescienceandpolicy.com/national_stem_cell_Bank.html

42 Although not unambiguously 'cosmetic', for a recent report see http://news.bbc.co.uk/1/hi/health/3473889.stm

43 The report is available online here http://www.publications.parliament.uk/pa/cm200203/cmselect/cmtrdind/87/87.pdf with the government response here http://www.publications.parliament.uk/pa/cm200203/cmselect/cmtrdind/1282/1282.pdf

Whilst the recent regulation of the Stem Cell Bank shows signs of introducing a more interdisciplinary representation this is something that requires more work both in the UK and internationally. For example to improve the social science and ethical representation on both advisory committees and as advisors to the governmental committees would be in line with the recent interdisciplinary funding of SCR which extended *across* the UK research councils.

Ultimately any process of regulation in this area should be judged by its ability to see the issue from a multiplicity of different, often critical, perspectives. This can only serve to bolster the robustness and rigour of regulation. The UK has the longest standing tradition of constructing measures for the regulation of stem cell and embryonic research. Instead of falling for the temptation of self-congratulation the UK regulatory process will be best served by a continuation of healthy self-reflexive critique aimed at further refining both interdisciplinary inspection and public inclusiveness.

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